

Claims 3, 27, and 30 are objected to as being dependent on a rejected base claim. These claims have been rewritten in independent form as suggested by the Examiner. It is believed that these claims are now in condition for allowance. Claim 24 is allowed.

Applicant requests that the case as amended be allowed. Alternately, it is requested that the final rejection entered in the previous rejection be withdrawn as premature and the present amendment to claim 17 be entered.

#### The Final Rejection

The rejected claims stand on rejected based on references cited for the first time in the final rejection. The office action states that the new grounds of rejection were necessitated by Applicant's amendment. This statement and the resultant final rejection is traversed.

MPEP 707.07(a) states as follows:

A second or any subsequent action on the merits in any application . . . should not be made final if it includes a rejection, on prior art not of record, of *any claim* amended to include limitations which should *reasonably have been expected to be claimed*.

(emphasis added).

The Examiner's attention is first directed to independent claim 25, which was originally rejected as anticipated by Kalfas. The only amendment to this claim was to clarify that the position indicator was human readable. The claims as filed (*see, e.g.*, claims 6, 16, 23, 29, 31) and the specification (*see, e.g.*, page 7 lines 23-28) were both replete with references to this feature.

Claim 17 was also rejected as anticipated by Kalfas. This claim was amended, in pertinent part, to include the tool-mounted position indicator feature of dependent claim 18. The claims as filed were replete with references to this feature (*see, e.g.*, claims 3, 18, 24, 25), as were the specification and drawings (*see, e.g.*, specification page 7 lines 23-27 and Figs. 1A, 2, 3, and 4). Claim 17 was also amended to clarify that the position indicator provides an indication to a human operator. As described above, both the claims as filed and the specification were both

replete with references to this feature.

Independent claims 1, 24, and 26 contained similar amendments.

Inasmuch as the claims presented in the first amendment were presaged by the claims as filed and by the specification, it cannot fairly be said that the amendments should not reasonably have been expected by the Examiner. Nor can applicant fairly be said to have switched from one subject matter to another in a subsequent amendment. Indeed, the present office action relies on entirely new references to support a final rejection of claims directed to subject matter which is substantially similar, if not identical, to the original claims. The premature final rejection defeats the entire purpose of the prosecution process and has prevented the development of any clear issue regarding patentability of the present claims:

Before final rejection is order a clear issue should be developed between the examiner and the applicant. To bring the prosecution to as speedy conclusion as possible and at the same time deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied . . . . Switching from . . . one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat the goal of reaching a clearly defined issue for an early termination . . .

MPEP 706.07.

Accordingly, applicant requests that, in the event that the present amendments are not admitted and the case allowed, the final rejection entered in the office action mailed October 16, 1998 be withdrawn.

#### The Present Claims

**Claim 1** stands rejected as anticipated by Barrick. The office action states that Barrick's fluoroscope is a means for indicating to a human the difference between the actual and desired positions of the tool and that the optical digitizer is a means for determining the actual position of the means for indicating.

Barrick's fluoroscope 200 is not a means for indicating to a human the difference

between the actual and desired positions of the tool. The fluoroscope 200 contains an x-ray source 231 and detector 232. The resultant fluoroscopic image is displayed in human readable form on a separate monitor screen 400 (not shown). While Barrick teaches that the optical digitizer 212 is used to determine the position of the fluoroscope 200, Barrick fails to disclose or suggest that the digitizer 212 be used to determine an actual position of the human readable monitor screen 400.

Regarding dependent claim 2, the office action cites Barrick column 6, lines 13-23 to the effect that the drill 301 is characterized by a tool reference frame and that the difference is indicated in relation to the tool reference frame. In fact, Barrick's drill 301 contains LEDs 300 which are used by the optical digitizer 212 to determine the position of the drill. The cited language teaches that this information is used to display the position of the drill superimposed on the image on the monitor screen, irrespective of how the image or monitor may be oriented. Stated another way, the position of the drill is shown in the image reference frame – position difference information is not displayed with respect to the tool reference frame as required by claim 2.

With continuing reference to claims 1-3 and further reference to claims 4-15, 31, and 33-35, the office action states that the LED's 201, 202 on Barrick's fluoroscope indicate a direction in which the tool should be moved to reach a desired position. In fact, the LEDs 201, 202 provide a signals indicative only of the actual position of the tool with respect to the optical localizer 212. Even then, this information is not provided in a form understandable to a human. Only after further processing and with additional information (such as the desired position, the relative relationships between the various reference frames, and the like) can the direction in which the tool should be moved be displayed in human readable form on Barrick's monitor 400 (not shown). To clarify any confusion in this regard, claim 1 was previously amended to require that the means for indicating provide the information in a form understandable to a human.

More specifically to claim 10, the office action fails to provide any indication whatsoever as to the corresponding features in Barrick. Lacking this information, applicant is unable to

respond to the rejection. More specifically to claims 13, 21 and 34, the office action fails to indicate what in Barrick corresponds to the mode indicator or the position indicator. Even if Barrick's LED's are considered to be position indicators - which is traversed above - there is no teaching that the LED's include a mode indicator or that there is a mode selection step. Turning to claim 15, Barrick fails to disclose or suggest that the LEDs be mounted in a plane perpendicular to the tool's pointing axis (see Barrick Figure 3). Applicant requests that, in the event that these claims are not allowed, the Examiner provide a statement of reasons for the rejection and an opportunity for applicant to respond in a meaningful way or, if appropriate, amend the claim.

For at least the reasons set forth above, it is requested that the rejection of claims 1, 2, 4-15, 31, and 33-35 be withdrawn.

Claims 17, 19-23, and 25 stand rejected as anticipated by Cartmell.

**Claim 17** has been amended to further require a means for communicating a position of the tool to an image guided surgery system. Cartmell's device is used to track the location of a catheter by providing an indication of the distance between the probe and the catheter and the orientation of the catheter. It is submitted that Cartmell fails to disclose or suggest the means for communicating added herein.

**Claim 20**, which depends from claim 17, further requires a means for determining the relative orientations of the at least indicator and the anatomy of the patient. In contrast, Cartmell's device determines the relative orientations of the probe and the catheter, and fails to disclose or suggest the means required by claim 20.

**Claim 25** is directed to a surgical tool which includes a plurality of infrared emitters mounted to the tool and at least one human readable position indicator mounted to the tool. The office action states that Cartmell discloses a surgical tool having a plurality of infrared emitters mounted to the tool. In fact, Cartmell's probe 2 contains a rotating magnetic transmit coil which generates a magnetic field which interacts with the receive coil. Because Cartmell's receive coil

is located within the body, substituting infrared emitters and detectors for Cartmell's magnetic coils would destroy the functionality of Cartmell's device. Hence, claim 25 is neither anticipated nor suggested by Cartmell.

**Claim 16** stands rejected as obvious over Barrick in view of Bucholz. The office action indicates that Bucholz' sonic emitters 48, 50 provide an audible indication useful to a human. In fact, Bucholz' sonic emitters provide signals indicative only of the actual position of the emitters with respect to the receivers 14. Even then, this information is not provided in a form understandable to a human. While substituting Barrick's LED's with Bucholz' sonic emitters might lead to an alternate localizing system, it would not provide a human readable, audible indication of the difference between the actual and desired positions of the tool.

**Claim 29** stands rejected as obvious over Barrick. The office action states that, while Barrick does not use the use of a blink rate or color of an indicator visible to a user, it would have been obvious to so modify Barrick's indicator to provide a human readable indication of the direction in which the tool must be moved. As noted above, however, Barrick's LEDs do not provide a signal useful to a human – they provide a signal readable by the optical digitizer 212. Hence, modification of Barrick's machine readable LED's to vary their blink rate or color to provide a human readable indication of the direction is in no way suggested by Barrick.

For the reasons set forth above, it is submitted that claims 1, 2, 4-17, 19-23, 25, 26, 28, 29, 31, and 33-35 are directed to patentable subject matter.

In the event that the Examiner would find it useful to discuss any aspect of this application or the prior art in further detail, applicant would welcome a telephonic interview.

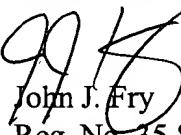
A check to cover the additional independent claims added by the present amendment is enclosed.

### Conclusion

The indication that claims 3, 27, and 30 are directed to patentable subject matter is appreciated. As suggested by the Examiner, these claims have been placed in independent form including the limitations, if any, of intervening claims. It is believed that these claims are now in condition for allowance.

As more fully set forth above, it is believed that claims 1, 2, 4-17, 19-23, 25, 26, 28, 29, 31, and 33-35 distinguish patentably and unobviously over the prior art of record. An indication of allowability directed to these claims is earnestly solicited. In the alternative, it is requested that the amendment of claim 17 be entered and the final rejection of these claims withdrawn.

Respectfully submitted,



John J. Fry  
Reg. No. 35,873

Picker International, Inc.  
595 Miner Road  
Cleveland, OH 44143

440 473-3455